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RAYMOND W. GREEN
Registered Representative

Signature

Date of Signature: April 13, 2005

PATENT
BHG&L Case 8627/405

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Kieran P. J. Murphy	:	Cook Case PA-5281
Serial No.:	09/594,685	:	
Filed:	June 16, 2000	:	Group Art Unit: 3732
For:	APPARATUS FOR STRENGTHENING VERTEBRAL BODIES	:	Examiner: Eduardo C. Robert

MAIN BRIEF ON APPEAL TO THE
BOARD OF PATENT APPEALS AND INTERFERENCES

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Sir:

(1) REAL PARTY IN INTEREST

The inventor has not assigned his entire interests in the invention, and hence a real party in interest is Applicant / Appellant Kieran P. J. Murphy. The inventor has, however, granted rights in the invention (not shown by documents of record in the Patent and Trademark Office) to Cook Incorporated of Bloomington, Indiana, which is another real party in interest.

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(3) RELATED APPEALS AND INTERFERENCES

There is no related pending or decided appeal or interference. A prior appeal in this Application resulted in prosecution being reopened on March 24, 2004, before an Examiner's Answer was written, and before transfer of the Application to the Board for consideration of the Appeal.

(4) STATUS OF CLAIMS

The claims presented are Claims 1-23. All claims are rejected. No claims have been cancelled. No claims have been allowed, although Claims 22 and 23 have been indicated to be drawn to allowable subject matter. The rejection of all claims is appealed.

(5) STATUS OF AMENDMENTS

In response to the Office Action of March 24, 2004, Applicant filed a timely Amendment on July 27, 2004, which has been entered. A copy of the claims submitted on July 27, 2004, is attached as Appendix A.

An amendment was filed February 10, 2005, in response to the Final Rejection of November 15, 2004. In an Advisory Action mailed in this Application on March 10, 2005, the Examiner stated that the proposed Amendment filed February 10, 2005, would not be entered, because it was deemed to raise new issues that would require further consideration and/or search, and because it was deemed to raise the issue of new matter; and that for purposes of appeal, the proposed amendment would not be entered, and Claims 1-23 would be continued to be rejected.

A Request for Reconsideration of the denial of entry of the Amendment was filed April 5, 2005.

A copy of the claims submitted February 10, 2005, is attached as Appendix B.

(6) SUMMARY OF CLAIMED SUBJECT MATTER

In the Claims filed July 27, 2004, Claims 1, 17, 20 and 21 are independent. In the Claims proposed February 10, 2005, Claims 1, 17, 20, 21, 22 and 23 are independent. Applicant asserts that the scope of the Claims was not changed, so that the subject matter claimed can be described in the same paragraphs, regardless of whether or not the Amendment filed February 10, 2005, is entered.

(a) Independent Claim 1 and Dependent Claims 2-16.

The invention as claimed in Claims 1-16 is a tray of vertebroplasty components for use in performing vertebroplasty (surgery of the vertebrae), including a collection of components that Applicant has found to be useful for a surgeon intending to perform vertebroplasty. The components include a local anaesthesia assembly (Figure 4, item 61); a bone cement assembly

(item 80); a surgical cutting instrument such as a scalpel (item 71); and a device for injection of hardenable liquid biomaterial into a vertebral body, such as a vertebroplasty needle (item 73). Components recited in dependent claims 2-16 include a container of a local anaesthesia (item 63); a local anaesthesia aspiration syringe (item 65); a local anaesthesia aspiration needle (item 67); a local anaesthesia injection needle (item 69); a container of a liquid monomer (item 82); a monomer aspiration needle (item 85); a monomer aspiration syringe (item 84); a mixing bowl (item 86); a mixing spatula (item 88); a container of polymer powder such as methylmethacrylate (item 90); and an opacifier (item 92).

No prior art reference or combination of references applied by the Examiner teaches or suggests the combinations of components claimed in claims 1-16.

(b) Independent Claim 17 and Dependent Claims 18-19.

The invention as claimed in Claims 17-19 is a vertebroplasty kit (Figure 4, item 55) comprising two trays (items 57 and 59) of vertebroplasty components, which may be individually assembled and packaged (claim 18) and kept sterile until use in performing vertebroplasty (claim 19). The two trays are arranged so that the first tray of components can be used to perform a first vertebroplasty injection through a first pedicle of a vertebral body (claim 17, lines 3-4), and then the second tray of components can either (a) be used to perform a second vertebroplasty injection through a second pedicle of a vertebral body, if it is determined that the first vertebroplasty injection did not sufficiently strengthen the vertebral body; or (b) remain sterile for use in another vertebral body if said first vertebroplasty injection is determined to have sufficiently strengthened the vertebral body (claim 17, lines 7-9).

Lazarus, the reference applied to allegedly anticipate Claims 17-19, does not teach 'vertebroplasty injection components' as recited in claim 17. Furthermore, no prior art reference or combination of references applied by the Examiner teaches or suggests the two-tray configuration claimed in claims 17-19, arranged so that the first tray of components can be used to perform a first vertebroplasty injection, and then the second tray of components can either (a) be used to perform a second vertebroplasty injection, or (b) remain sterile for use in another vertebral body.

(c) Independent Claim 20.

Claim 20 recites the same ultimate components as Claim 1, but not the intermediate local anaesthesia assembly and bone cement assembly.

No prior art reference or combination of references applied by the Examiner teaches or suggests the combinations of components claimed in claim 20.

(d) Independent Claim 21.

Claim 21 recites the same hardware components as Claim 1, but not the materials that are mixed to make the cement (monomer, polymer powder and opacifier).

No prior art reference or combination of references applied by the Examiner teaches or suggests the combinations of components claimed in claim 21.

(e) Claim 22.

Claim 22, originally dependent from Claim 17, but proposed to be rewritten in independent form in the Amendment filed February 10, 2005, recites a vertebroplasty kit as claimed in Claim 17, but then also recites particular vertebroplasty / surgical components that are present in the kit.

No prior art reference or combination of references applied by the Examiner teaches or suggests the combinations of components claimed in claim 22; and in fact the Examiner indicated in the Final Rejection mailed November 15, 2004, that Claims 22 and 23 were considered indefinite and rejected under 35 USC 112, second paragraph, in that it was unclear whether the recited components were present in the first and second tray in combination, or if each of the first and second trays contained the recited components; but that for examination purposes, the claims had been construed to recite that each of the first and second trays contained the recited components (page 2); and that Claims 22 and 23 would be allowable if rewritten to overcome the rejection under 35 USC 112, second paragraph, and to include all of the limitations of the base claim and any intervening claims (page 10.)

(f) Claim 23.

Claim 23, originally dependent from Claim 17, but proposed to be rewritten in independent form in the Amendment filed February 10, 2005, recites a vertebroplasty kit as

claimed in Claim 17, but then also recites particular vertebroplasty / surgical components that are present in the kit. The vertebroplasty / surgical components recited in Claim 23 are a subset of the vertebroplasty / surgical components recited in Claim 22.

No prior art reference or combination of references applied by the Examiner teaches or suggests the combinations of components claimed in claim 22; and in fact the Examiner indicated in the Final Rejection mailed November 15, 2004, that Claims 22 and 23 were considered indefinite and rejected under 35 USC 112, second paragraph, in that it was unclear whether the recited components were present in the first and second tray in combination, or if each of the first and second trays contained the recited components; but that for examination purposes, the claims had been construed to recite that each of the first and second trays contained the recited components (page 2); and that Claims 22 and 23 would be allowable if rewritten to overcome the rejection under 35 USC 112, second paragraph, and to include all of the limitations of the base claim and any intervening claims (page 10.)

(g) Amendments to the Claims

In the Amendment filed February 10, 2005, Claims 1, 17 and 20-23 were proposed to be amended by changing recitations of "vertebroplasty components" to recite "vertebroplasty and surgical components"; dependent Claims 22 and 23 were proposed to be rewritten in independent form, to include all of the limitations of the base claim and any intervening claims; and Claims 22 and 23 were also proposed to be amended to explicitly recite and clarify that the recited vertebroplasty injection and surgical components are those contained in *each tray*, as assumed by the Examiner for purposes of Examination.

It is Applicant's position that the Amendment filed February 10, 2005, if entered, would not change the scope of the Claims.

In the Final Rejection, the Examiner stated that in the Declaration filed July 24, 2004, the expert declarant states that a syringe and needle for injecting anesthetic are general surgical components, but in Applicant's claims (for example, Claim 22), a local anaesthesia injection needle is considered a vertebroplasty injection component. (Final Rejection of November 15, 2004, pages 6-7.)

Responsive to this observation, the amendment changing recitations of "vertebroplasty components" to "vertebroplasty and surgical components" was proposed to remove a point of

contention, although it was totally unnecessary, and did not change the scope of the claims, because vertebroplasty is a type of surgical procedure. Hence, vertebroplasty components *are* surgical components – specialized surgical components.

(7) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(a) Claims 22 and 23 were rejected as indefinite under 35 USC 112, second paragraph.

(b) Claims 17-19 are rejected as anticipated by Lazarus, U.S. Patent 4,128,173, under 35 USC 102(b).

(c) Claims 1-16, 20 and 21 are rejected as obvious in view of Vagley, U.S. 6,158;437, and also as obvious in view of Vagley in view of eleven secondary references (Shanley, U.S. 5,626,230; MacLeod et al., U.S. 5,506,257; Smith et al., U.S. 5,690,618; Arlers, U.S. 3,910,273; Racz, U.S. 5,817,074; Jiang et al., U.S. 5,847,046; Singer, U.S. 5,147,308; Draenert, U.S. 5,645,307; Haynie, U.S. 5,240,415; Hertzmann et al. U.S. 5,084,043; and Baker U.S. 4,554,686) under 35 USC 103(a).

(8) ARGUMENT

(a) The Rejection of Claims 22 and 23 as Indefinite Should be Reversed.

Claims 22 and 23 were rejected as indefinite under 35 USC 112, second paragraph, because in the then-pending versions of those claims, the Examiner was not sure if the recited components were present collectively in both trays, or if each (the first and the second) tray contained the recited components; but that for examination purposes, the claims had been construed to recite that each of the first and second trays contained the recited components (Final Rejection of November 15, 2004, page 2).

It is submitted that the Examiner's interpretation is the only reasonable one, and that the Claims are not indefinite. Claims 22 and 23 were proposed to be amended, however, to clarify that the components are those contained in each tray. Whether or not the Amendment filed February 10, 2005, is entered, the rejection should be reversed.

(b) The Rejection of Claims 17-19 as Anticipated by Lazarus Should be Reversed, because Lazarus Does Not Teach 'Vertebroplasty Injection Components' as recited in claim 17.

Claims 17-19 are rejected as anticipated by Lazarus, U.S. Patent 4,128,173. For the Lazarus patent to anticipate the claims, every element recited in these claims must be present in the Lazarus patent.

The Examiner does not take proper account of a point made in the Appeal Brief filed January 12, 2004, and reiterated in the last two Amendments, namely that the "Lazarus apparatus does not have 'vertebroplasty injection components', recited in claim 17, lines 3 and 5, in either tray."

In construing terms in claims, the words used should be given their ordinary meaning to persons of ordinary skill in the art. Neither the Examiner nor the undersigned attorney is a person of ordinary skill in the art to which this invention pertains. The inventor, however, Dr. Kieran Murphy, is a person of more than ordinary skill in the art. Presented with the Amendment filed July 27, 2004, was a Declaration Under 37 CFR 1.132, explaining that the Lazarus apparatus does not have "vertebroplasty injection components", recited in claim 17, lines 3 and 5, in either tray, as that term is understood by persons of ordinary skill in the art. (See Declaration at pages 3-5, paragraphs 7-12.) A copy of the Declaration Under 37 CFR 1.132 is enclosed as Appendix C.

In response to Applicant's previous amendment and the Declaration Under 37 CFR 1.132, the Examiner repeats *verbatim* (Final Rejection of November 15, 2004, page 5) a paragraph from page 5 of the Office Action of March 24, 2004, concluding that "it is clear that each tray [of Lazarus] include[s] a[n] injection component and they can perform a function in spinal surgery if one so desire[s]." The Examiner ignores the explanation in the Declaration why the Lazarus components are not "vertebroplasty injection components", dismissing it as "opinion" of a party who has an interest in the outcome of the case, and lacking in "facts". The Examiner ignores the facts recited in the Declaration in Paragraphs 7-12, *e.g.*, that vertebroplasty injection components are a different size than the Lazarus needles.

The Examiner then makes a point made previously, that the manner in which a device is to be employed does not differentiate the apparatus from prior art apparatus having the structural limitations. However, as explained in the Declaration, the recitation "vertebroplasty injection

components" is more than an intended use; it designates for example needles sufficiently robust for injection of bone cement. The Examiner says "facts" are events, acts or occurrences which have actually taken place, and indeed, that is what *historical* facts are. However, it is also a fact, as pointed out in the Declaration, that vertebroplasty injection needles need to be sufficiently robust for injection of bone cement. So the Examiner ignores the facts stated in the Declaration, and *based on no facts at all*, elevates his own opinion over that of the expert. This is error.

The Examiner points out (Final Rejection of November 15, 2004, page 7) that some of the items recited in Applicant's claims are general surgical apparatus. The claims were proposed to be amended accordingly, even though the amendment was not deemed to be necessary, and was not deemed to change the scope of the Claims. Other items recited in Applicant's claims, however, are vertebroplasty components, not taught or suggested by the applied references.

Accordingly, the rejection of Claims 17-19 should be reversed.

(c) The Rejections of Claims 1-16, 20 and 21 as Obvious from Vagley or from Vagley in View of Eleven Other References Should be Reversed, Because the Prior Art does not Teach or Suggest the *Combinations* Claimed in Claims 1-16, 20 and 21.

Claims 1-16, 20 and 21 are rejected as obvious in view of Vagley, U.S. 6,158,437, and also as obvious in view of Vagley in view of eleven secondary references (Shanley, MacLeod et al., Smith et al., Arlers, Racz, Jiang et al., Singer, Draenert, Haynie, Hertzmann et al. and Baker).

The Examiner has used Applicant's claims as a shopping list to find patents that teach each *element* (or something he considers to be *like* each element) in the combination, but has not cited or applied a reference that teaches or suggests the *combination* itself.

Claims 1-16, 20 and 21 are directed to trays of vertebroplasty and surgical components for use in performing vertebroplasty. The Vagley patent discloses a tray and says things *other than* vertebroplasty components should be on the tray. So Vagley does not teach or suggest *Applicant's* combination, Vagley teaches a *different* combination.

The Declaration Under 37 CFR 1.132 filed with the last Amendment explains why the *combinations* claimed in Claims 1-16, 20 and 21 would not have been obvious to a person of ordinary skill in the art, either from Vagley alone or from Vagley in view of the eleven secondary references applied in another rejection. (See Declaration at page 5, paragraphs 13-14.)

In response to Applicant's previous amendment and the Declaration filed with the last Amendment, the Examiner says (pages 8-9 of Final Rejection) that Vagley discloses that his tray can be customized to cater to the preference of a specific surgeon. This does not amount to a teaching or suggestion of the *particular combinations* claimed by Applicant.

Accordingly, the rejections of Claims 1-16, 20 and 21 should be reversed.

(9) CONCLUSION

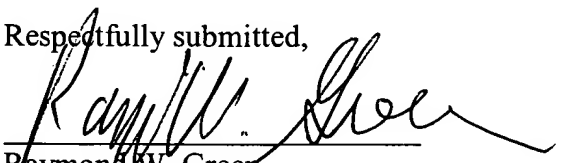
Claims 17-19, 22 and 23 recite "vertebroplasty injection components", which are not present in the Lazarus patent. Applicant has filed the Declaration Under 37 CFR 1.132 of the inventor, Dr. Kieran Murphy, showing that the Lazarus patent does not teach "vertebroplasty injection components" as that term is understood by persons of ordinary skill in the art.

Claims 1-16, 20 and 21 recite combinations, which neither Vagley nor any of the secondary references teach or suggest.

Claims 22 and 23 were indicated to be allowable if rewritten to overcome formal rejections and eliminate reference to rejected claims. Claims 22 and 23 were proposed to be amended to overcome formal rejections and eliminate reference to rejected claims, but have not been allowed.

Accordingly, the Application appears to be in order for allowance, both as to form and in view of the prior art. All rejections applied by the Examiner should therefore be REVERSED.

Respectfully submitted,



Raymond W. Green
Registration No. 24,587

BRINKS HOFER GILSON & LIONE
P.O. Box 10395
Chicago, Illinois 60610
312-321-4222

April 13, 2005

(10) APPENDIX A – Claims presented July 27, 2004

Claim 1 (previously presented): A tray of vertebroplasty components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia assembly for producing a reversible loss of sensation in a surgical area proximate to a vertebral body;

a bone cement assembly for preparation of a hardenable liquid biomaterial for strengthening said vertebral body;

a surgical cutting instrument for providing cutaneous incision in said surgical area proximate to said vertebral body; and

a device for injection of said hardenable liquid biomaterial into said vertebral body.

Claim 2 (previously presented): The tray according to claim 1, wherein said local anaesthesia assembly includes at least one container of a local anaesthesia.

Claim 3 (previously presented): The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia aspiration syringe.

Claim 4 (previously presented): The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia aspiration needle.

Claim 5 (previously presented): The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia injection needle.

Claim 6 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one container of a liquid monomer.

Claim 7 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one monomer aspiration needle.

Claim 8 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one monomer aspiration syringe.

Claim 9 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one mixing bowl.

Claim 10 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one mixing spatula.

Claim 11 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one container of polymer powder.

Claim 12 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes an opacifier.

Claim 13 (previously presented): The tray according to claim 11, wherein said polymer powder is methylmethacrylate.

Claim 14 (previously presented): The tray according to claim 11, wherein said polymer powder in said hardenable liquid biomaterial is from about five grams to about forty grams of methylmethacrylate.

Claim 15 (previously presented): The tray according to claim 11, wherein said surgical cutting instrument is a scalpel.

Claim 16 (previously presented): The tray according to claim 11, wherein said device for injection is a vertebroplasty needle.

Claim 17 (previously presented): A vertebroplasty kit for use in performing vertebroplasty, said vertebroplasty kit comprising:

a first tray of vertebroplasty injection components for performing a first vertebroplasty injection through a first pedicle of a vertebral body;

a second tray of vertebroplasty injection components for performing a second vertebroplasty injection through a second pedicle of said vertebral body, such that said second tray of vertebroplasty injection components can remain sterile for use in another vertebral body if said first vertebroplasty injection sufficiently strengthens said vertebral body.

Claim 18 (previously presented): The kit according to claim 17, wherein said first tray and said second tray are individually assembled and packaged.

Claim 19 (previously presented): The kit according to claim 18, wherein said first tray and said second tray are sterile until use in performing vertebroplasty.

Claim 20 (previously presented): A tray of vertebroplasty components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia;
a local anaesthesia aspiration syringe;
a local anaesthesia aspiration needle;
a local anaesthesia injection needle;
a liquid monomer;
a monomer aspiration needle;
a monomer aspiration syringe;
a mixing bowl;
a mixing spatula;
a polymer powder;
an opacifier;
a scalpel; and
a vertebroplasty needle.

Claim 21 (previously presented): A tray of vertebroplasty components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia;

a local anaesthesia aspiration syringe;

a local anaesthesia aspiration needle;

a local anaesthesia injection needle;

a monomer aspiration needle;

a monomer aspiration syringe;

a mixing bowl;

a mixing spatula;

a scalpel; and

a vertebroplasty needle.

Claim 22 (new): The kit according to claim 17, wherein the vertebroplasty injection components comprise:

a local anaesthesia;

a local anaesthesia aspiration syringe;

a local anaesthesia aspiration needle;

a local anaesthesia injection needle;

a liquid monomer;

a monomer aspiration needle;

a monomer aspiration syringe;

a mixing bowl;

a mixing spatula;

a polymer powder;

an opacifier;

a scalpel; and

a vertebroplasty needle.

Claim 23 (new): The kit according to claim 17, wherein the vertebroplasty injection components comprise:

a local anaesthesia;

a local anaesthesia aspiration syringe;

a local anaesthesia aspiration needle;

a local anaesthesia injection needle;

a monomer aspiration needle;

a monomer aspiration syringe;

a mixing bowl;

a mixing spatula;

a scalpel; and

a vertebroplasty needle.

(11) **APPENDIX B – Claims presented February 10, 2005**

Claim 1 (currently amended): A tray of vertebroplasty and surgical components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia assembly for producing a reversible loss of sensation in a surgical area proximate to a vertebral body;

a bone cement assembly for preparation of a hardenable liquid biomaterial for strengthening said vertebral body;

a surgical cutting instrument for providing cutaneous incision in said surgical area proximate to said vertebral body; and

a device for injection of said hardenable liquid biomaterial into said vertebral body.

Claim 2 (previously presented): The tray according to claim 1, wherein said local anaesthesia assembly includes at least one container of a local anaesthesia.

Claim 3 (previously presented): The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia aspiration syringe.

Claim 4 (previously presented): The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia aspiration needle.

Claim 5 (previously presented): The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia injection needle.

Claim 6 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one container of a liquid monomer.

Claim 7 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one monomer aspiration needle.

Claim 8 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one monomer aspiration syringe.

Claim 9 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one mixing bowl.

Claim 10 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one mixing spatula.

Claim 11 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes at least one container of polymer powder.

Claim 12 (previously presented): The tray according to claim 1, wherein said bone cement assembly includes an opacifier.

Claim 13 (previously presented): The tray according to claim 11, wherein said polymer powder is methylmethacrylate.

Claim 14 (previously presented): The tray according to claim 11, wherein said polymer powder in said hardenable liquid biomaterial is from about five grams to about forty grams of methylmethacrylate.

Claim 15 (previously presented): The tray according to claim 11, wherein said surgical cutting instrument is a scalpel.

Claim 16 (previously presented): The tray according to claim 11, wherein said device for injection is a vertebroplasty needle.

Claim 17 (currently amended): A vertebroplasty kit for use in performing vertebroplasty, said vertebroplasty kit comprising:

a first tray of vertebroplasty injection and surgical components for performing a first vertebroplasty injection through a first pedicle of a vertebral body;

a second tray of vertebroplasty injection and surgical components for performing a second vertebroplasty injection through a second pedicle of said vertebral body, such that said second tray of vertebroplasty injection components can remain sterile for use in another vertebral body if said first vertebroplasty injection sufficiently strengthens said vertebral body.

Claim 18 (previously presented): The kit according to claim 17, wherein said first tray and said second tray are individually assembled and packaged.

Claim 19 (previously presented): The kit according to claim 18, wherein said first tray and said second tray are sterile until use in performing vertebroplasty.

Claim 20 (currently amended): A tray of vertebroplasty and surgical components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia;
a local anaesthesia aspiration syringe;
a local anaesthesia aspiration needle;
a local anaesthesia injection needle;
a liquid monomer;
a monomer aspiration needle;
a monomer aspiration syringe;
a mixing bowl;
a mixing spatula;
a polymer powder;
an opacifier;
a scalpel; and
a vertebroplasty needle.

Claim 21 (currently amended): A tray of vertebroplasty and surgical components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia;

a local anaesthesia aspiration syringe;

a local anaesthesia aspiration needle;

a local anaesthesia injection needle;

a monomer aspiration needle;

a monomer aspiration syringe;

a mixing bowl;

a mixing spatula;

a scalpel; and

a vertebroplasty needle.

Claim 22 (currently amended): A vertebroplasty kit for use in performing vertebroplasty, said vertebroplasty kit comprising:

a first tray of vertebroplasty injection and surgical components for performing a first vertebroplasty injection through a first pedicle of a vertebral body;

a second tray of vertebroplasty injection and surgical components for performing a second vertebroplasty injection through a second pedicle of said vertebral body, such that said second tray of vertebroplasty injection components can remain sterile for use in another vertebral body if said first vertebroplasty injection sufficiently strengthens said vertebral body [The kit according to claim 17],

wherein said first tray and said second tray each contain the following vertebroplasty injection and surgical components [comprise]:

a local anaesthesia;

a local anaesthesia aspiration syringe;

a local anaesthesia aspiration needle;

a local anaesthesia injection needle;

a liquid monomer;

a monomer aspiration needle;

a monomer aspiration syringe;

a mixing bowl;

a mixing spatula;

a polymer powder;

an opacifier;

a scalpel; and

a vertebroplasty needle.

Claim 23 (currently amended): A vertebroplasty kit for use in performing vertebroplasty, said vertebroplasty kit comprising:

a first tray of vertebroplasty injection and surgical components for performing a first vertebroplasty injection through a first pedicle of a vertebral body;

a second tray of vertebroplasty injection and surgical components for performing a second vertebroplasty injection through a second pedicle of said vertebral body, such that said second tray of vertebroplasty injection components can remain sterile for use in another vertebral body if said first vertebroplasty injection sufficiently strengthens said vertebral body [The kit according to claim 17],

wherein said first tray and said second tray each contain the following vertebroplasty injection and surgical components [comprise]:

a local anaesthesia;

a local anaesthesia aspiration syringe;

a local anaesthesia aspiration needle;

a local anaesthesia injection needle;

a monomer aspiration needle;

a monomer aspiration syringe;

a mixing bowl;

a mixing spatula;

a scalpel; and

a vertebroplasty needle.

(12) EVIDENCE APPENDIX

Appended hereto is the Declaration Under 37 CFR 1.132 by Kieran P. J. Murphy signed July 26, 2004, and of record in this Application file (filed July 27, 2004).

With respect to 37 CFR 41.37(c)(1)(ix), in the Final Rejection mailed November 15, 2004, in this Application, the Examiner states that the Murphy Declaration was considered (page 6).